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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,240	08/01/2003	Thomas H. Turpen	N9525	3290
7590	03/18/2004		EXAMINER	
Waddey & Patterson, P.C. Bank of America Plaza 414 Union Street, Suite 2020 Nashville, TN 37219			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/632,240	TURPEN ET AL.
	Examiner	Art Unit
	Jeffrey E. Russel	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 August 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 35-43 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 35-43 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 01 August 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>09/02/03</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

1. The Sequence Listing filed August 1, 2003 has been approved.
2. The disclosure is objected to because of the following informalities: The status of the parent grandparent applications recited in the preliminary amendment to page 1, lines 4-7, of the specification should be updated. Appropriate correction is required.
3. Claim 37 is objected to because of the following informalities: Claim 37 appears to be missing a phrase, possibly "once before said separating step", after "at least". Appropriate correction is required.
4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).  
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
5. Claims 35 and 37-43 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,617,435. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '435 patent anticipate the instant claims.
6. Claims 35, 37, 39, 40, 42, and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent No. 6,441,147. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '147 patent anticipate instant claims 35, 39, 40, 42,

and 43. With respect to instant claim 37, it would have been obvious to one of ordinary skill in the art to repeat the vacuum infiltration step in the claimed method of the '147 patent because it is *prima facie* obvious to duplicate known process steps (see MPEP 2144.04(VI)(B)), and because duplication of the claimed vacuum infiltration step in the claimed method of the '147 patent would have been expected to increase recovery of the proteins and biomolecules of interest.

7. Claims 35, 42, and 43 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,284,875 in view of the Klement article. The '875 patent claims subjecting leaves to vacuum infiltration (see, e.g., claim 11, step (e), and claim 16, step (e)), but does not claim dissecting the plant leaf substantially along the midrib before the vacuum infiltrating step. The Klement article teaches that cutting leaves lengthwise parallel to the main vein facilitates withdrawal of intercellular fluid from the leaves by vacuum infiltration, and discloses blotting the infiltrated leaves prior to centrifugation. See page 1033, column 1. It would have been obvious to one of ordinary skill in the art to subject the plant leaves in the claimed method of the '875 patent to longitudinal shear prior to the vacuum infiltrating step because the Klement article teaches that longitudinal shearing of leaves is useful for vacuum infiltration.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

9. Claims 35, 40, 42, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by the De Wilde et al article. The De Wilde et al article teaches the recovery of an antibody and antibody fragments from transgenic plant leaf intercellular, i.e. interstitial, fluid by vacuum-infiltrating the leaves with a buffer contain Tris, centrifugation of the infiltrated leaves which have been transferred to a syringe, and immunoprecipitation from the intercellular fluid. The chains of the protein are targeted to the endoplasmic reticulum using a signal sequence. See,

e.g., the Abstract and page 235, column 1, first full paragraph, and page 235, paragraph bridging columns 1 and 2.

10. Claim 37 is rejected under 35 U.S.C. 103(a) as being obvious over the De Wilde et al article. Application of the De Wilde et al article is the same as in the above rejection of claims 35, 40, 42, and 43. The De Wilde et al article does not teach repeating the step of subjecting the plant tissue and buffer solution to a substantially vacuum environment. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to repeat the De Wilde et al article's vacuum infiltration step because it is *prima facie* obvious to duplicate known process steps (see MPEP 2144.04(VI)(B)), and because duplication of the vacuum infiltration step of the De Wilde et al article would have been expected to increase recovery of the antibodies or antibody fragments.

11. Claims 39 and 41 are rejected under 35 U.S.C. 102(b) as being obvious over the De Wilde et al article as applied in the rejection of claims 35, 40, 42, and 43 above, and further in view of the De Neve et al article. The De Neve et al article, cited at page 234, column 1, first full paragraph, of the De Wilde et al article, teaches that the transgenic plant is formed using a recombinant plant viral vector. See page 28 under "Constructs and transformation".

12. Claims 35, 37, and 39-43 are rejected under 35 U.S.C. 103(a) as being obvious over the De Wilde et al article as applied in the rejections of claims 35, 40, 42, and 43 above, or over the De Wilde et al article as applied in the rejection of claim 37 above, or over the De Wilde et al article in view of the De Neve et al article as applied in the rejection of claims 39 and 41 above, each further in view of the Klement article. The De Wilde et al article does not teach dissecting the plant leaf substantially along the midrib before the vacuum infiltrating step. The Klement

article teaches that cutting leaves lengthwise parallel to the main vein facilitates withdrawal of intercellular fluid from the leaves by vacuum infiltration, and discloses blotting the infiltrated leaves prior to centrifugation. See page 1033, column 1. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to subject the transgenic plant leaves of the De Wilde et al article to longitudinal shear prior to the vacuum infiltrating step because the Klement article teaches that longitudinal shearing of leaves is useful for vacuum infiltration.

13. Claims 35-37 and 43 are rejected under 35 U.S.C. 103(a) as being obvious over the Parent et al article. The Parent et al article teaches vacuum infiltrating Nicotinia tabacum leaves with an aqueous solution comprising Tris and 2-mercaptoethanol, blotting the leaves, and then subjecting them to centrifugation at 1000 x g. The intercellular fluid extract is subjected to electrophoresis in order to isolate proteins induced by tobacco mosaic virus. See, e.g., page 564, column 2, last paragraph, and page 565, column 1, first, fifth, and sixth full paragraphs. The Parent et al article teaches treating leaves which are cut with scissors into pieces of 4-5 cm<sup>2</sup> rather than treating whole plant leaves or plant leaves dissected substantially along the midrib thereof. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to treat whole leaves rather than cut leaves in the method of the Parent et al article with only the expected result that whole leaves will require longer periods of time than cut leaves to achieve the same degree of infiltration and interstitial fluid, and because it is *prima facie* obvious to omit a process step whose function is not desired. See MPEP 2144.04(II)(A). The Parent et al article does not teach repeating the step of subjecting the plant tissue and buffer solution to a substantially vacuum environment. It would have been obvious to one of ordinary

skill in the art at the time Applicants' invention was made to repeat the Parent et al article's vacuum infiltration step because it is *prima facie* obvious to duplicate known process steps (see MPEP 2144.04(VI)(B)), and because duplication of the vacuum infiltration step of the Parent et al article would have been expected to increase recovery of the proteins induced by the tobacco mosaic virus.

14. Claims 35-37 and 43 are rejected under 35 U.S.C. 103(a) as being obvious over the Parent et al article as applied in the obviousness rejection against claims 35-37 and 43 above, and further in view of the Klement article. The Parent et al article does not teach dissecting the plant leaf substantially along the midrib before the vacuum infiltrating step. The Klement article teaches that cutting leaves lengthwise parallel to the main vein facilitates withdrawal of intercellular fluid from the leaves by vacuum infiltration, and discloses blotting the infiltrated leaves prior to centrifugation. See page 1033, column 1. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to subject the plant leaves of the Parent et al article to longitudinal shear prior to the vacuum infiltrating step because the Klement article teaches that longitudinal shearing of leaves is useful for vacuum infiltration.

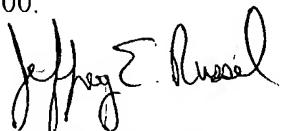
15. Claims 39-42 are rejected under 35 U.S.C. 103(a) as being obvious over the Parent et al article as applied against claims 35-37 and 43 above or over the Parent et al article in view of the Klement et al article as applied against claims 35-37 and 43 above, each further in view of the Trudel et al article. The Parent et al article does not teach recovering a protein which is a human lysosomal enzyme, an industrial enzyme,  $\alpha$ -galactosidase or an isozyme of  $\alpha$ -galactosidase, or glucocerebrosidase or an isozyme of glucocerebrosidase. The Trudel et al article teaches (see page 57, the paragraph bridging columns 1 and 2) recovering active hen egg white lysozyme

from transgenic tobacco using the vacuum infiltration method of reference 31, the Parent et al article. The Trudel et al article describes hen egg white lysozyme as a model enzyme and as having promising use as a pharmaceutical and preservative for food. See page 55, column 2, last paragraph. Therefore, the hen egg white lysozyme of the Trudel et al article is deemed to constitute an industrial enzyme. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to recover the active hen egg white lysozyme of the Trudel et al article in the process of the Parent et al article as modified above because the Trudel et al article uses the process of the Parent et al article to recover their lysozyme. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to recover human lysosomal enzyme,  $\alpha$ -galactosidase or an isozyme of  $\alpha$ -galactosidase, or glucocerebrosidase or an isozyme of glucocerebrosidase from transgenic tobacco by the vacuum infiltration method of the Parent et al article and the Trudel et al article because these enzymes are known enzymes which it would be desirable to produce transgenically because of the capability of producing larger amounts than by more traditional extraction from natural sources, and because the Trudel et al article describes its hen egg white lysozyme as a "model enzyme" and therefore its successful recovery by vacuum infiltration of transgenic tobacco suggests a reasonable expectation of success for the successful recovery by vacuum infiltration of other enzymes.

16. Concerning the Information Disclosure Statement filed September 2, 2003, the examiner has not signed or provided copies of duplicate citations, and the examiner has consolidated some citations in the attached Form PTO-892/Notice Of References Cited.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

March 15, 2004.